

FORM PTO-1390 MODIFIED	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY/AGENT NUMBER 4093-6
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 10/500,207
INTERNATIONAL APPLICATION NO. PCT/JP02/13650	INTERNATIONAL FILING DATE 26 December 2002	PRIORITY DATE CLAIMED 28 December 2001
TITLE OF INVENTION REMEDIES FOR ARTHRITIS		
APPLICANT(S) FOR DO/EO/US TAMURA, T. et al.		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The U.S. has been elected by the expiration of 19 months from the priority date (Article 31). 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (pages specification, claims & abstract (claims), sheets drawings). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation <ol style="list-style-type: none"> a. <input type="checkbox"/> of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (pages specification, claims & abstract (claims), sheets drawings, page Certificate of Translation). b. <input type="checkbox"/> of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. § 371(c)(5)). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. a. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s). b. <input type="checkbox"/> Declaration was submitted to the International Bureau during International Phase (see copies of Declaration (page Form PCT/RO/101 and Form PCT/IB/371 and first page of printed publication acknowledging receipt thereof attached). 10. See item 6.b. above. Items 11 To 20 below concern document(s) or information included: <ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information. English translation of International Preliminary Examination Report 		

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.53) 10/500,207		INTERNATIONAL APPLICATION NO. PCT/JP02/13650		ATTORNEY'S DOCKET NUMBER 4093-6	
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21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): -- Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO\$1110.00 -- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO\$950.00 -- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO\$790.00 -- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)\$750.00 -- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)\$100.00 <div style="text-align: right;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div> <div style="text-align: right;">\$</div> Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)). <div style="text-align: right;">\$ 0.00</div> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:20%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> <th style="width:20%;"></th> </tr> <tr> <td>Total Claims</td> <td>0 minus 20 =</td> <td>0</td> <td>X \$18.00</td> <td>\$ 0.00</td> </tr> <tr> <td>Independent Claims</td> <td>0 minus 3 =</td> <td>0</td> <td>X \$88.00</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="4">MULTIPLE DEPENDENT CLAIMS(S) (if applicable)</td> <td>\$300.00 \$ 0.00</td> </tr> <tr> <td colspan="4">Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$430.00/2 months; \$980.00/3 months)</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="4">TOTAL OF ABOVE CALCULATIONS =</td> <td>\$ 0.00</td> </tr> </table> <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. <div style="text-align: right;">SUBTOTAL =</div> <div style="text-align: right;">\$ 0.00</div> Processing fee of \$130.00, for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)). <div style="text-align: right;">+ 0.00</div> <div style="text-align: right;">TOTAL NATIONAL FEE =</div> <div style="text-align: right;">\$ 0.00</div> Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property + <div style="text-align: right;">\$ 40.00</div> Fee for Petition to Revive Unintentionally Abandoned Application (\$1370.00 - Small Entity = \$685.00) <div style="text-align: right;">\$ 0.00</div> <div style="text-align: right;">TOTAL FEES ENCLOSED =</div> <div style="text-align: right;">\$ 40.00</div> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:70%;"></td> <td style="width:10%;">Amount to be:</td> <td style="width:10%;"></td> <td style="width:10%;"></td> </tr> <tr> <td></td> <td>refunded</td> <td>\$</td> <td></td> </tr> <tr> <td></td> <td>Charged</td> <td>\$</td> <td></td> </tr> </table>					CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		Total Claims	0 minus 20 =	0	X \$18.00	\$ 0.00	Independent Claims	0 minus 3 =	0	X \$88.00	\$ 0.00	MULTIPLE DEPENDENT CLAIMS(S) (if applicable)				\$300.00 \$ 0.00	Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$430.00/2 months; \$980.00/3 months)				\$ 0.00	TOTAL OF ABOVE CALCULATIONS =				\$ 0.00		Amount to be:				refunded	\$			Charged	\$		CALCULATIONS PTO USE ONLY	
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a. ☒ A check in the amount of \$40.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 14-1140 in the amount of \$_____ to cover the above fees. A duplicate copy of this form is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.

d. ☒ The entire content of International Application No. **PCT/JP02/13650** and any U.S. and foreign application(s) corresponding thereto, and JP 2001-400677, referred to in this application is/are hereby incorporated by reference in this application.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

CORRESPONDENCE ADDRESS
Direct all correspondence to:

☒ **Customer Number:**

23117

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B. J. Sadoff
 NAME

Telephone: (703) 816-4000
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36,663
 REGISTRATION NUMBER

October 27, 2004
 Date

Translation

PATENT COOPERATION TREATY

PCT/JP2002/013650



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1442	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2002/013650	International filing date (day/month/year) 26 December 2002 (26.12.2002)	Priority date (day/month/year) 28 December 2001 (28.12.2001)
International Patent Classification (IPC) or national classification and IPC A61K 39/395, A61P 19/02, G01N 33/564		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 25 July 2003 (25.07.2003)	Date of completion of this report 06 February 2004 (06.02.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2002/013650

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP 02/13650

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-51	YES
	Claims		NO
Inventive step (IS)	Claims	1-51	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-51	YES
	Claims		NO

2. Citations and explanations

Document 1: Yukiko Kurihara et al., "Cooperation of endothelin-1 and FGF8 in Meckel's cartilage formation", Development, Growth & Differentiation, 2001, Vol. 43, Supplement, p. S109

Document 2: Craig A. Praul et al., "Effect of fibroblast growth factors 1, 2, 4, 5, 6, 7, 8, 9 and 10 on avian chondrocyte proliferation", Journal of Cellular Biochemistry, October 2001, Vol. 84, No. 2, pp. 359-366

Document 3: EP 799835 A2 (Kyowa Hakko Kogyo Co., Ltd.), 8 October 1997

Document 4: WO 00/62809 A1 (Kyowa Hakko Kogyo Co., Ltd.), 26 October 2000

Document 5: EP 882794 A2 (Kyowa Hakko Kogyo Co., Ltd.), 9 December 1998

Document 6: JP 2001-46066 A (Kyowa Hakko Kogyo Co., Ltd.), 20 February 2001

Novelty and inventive step

Document 1 discloses the fact that expression of Sox9, which contributes to joint formation, is suppressed by an anti-FGF-8 antibody.

Document 2 discloses the fact that FGF-8 causes

proliferation of chondrocytes.

Document 3 discloses monoclonal antibodies which react specifically with FGF-8 and inhibit the activity thereof, and indicates the use of such antibodies in the treatment of tumours.

Document 4 discloses the fact that tumour growth is suppressed by an anti-FGF-8 antibody.

Documents 5 and 6 disclose humanized antibodies.

However, none of the documents above discloses or suggests the possibility of treating arthritis with an anti-FGF-8 antibody.

Therefore, none of the documents cited in the international search report takes away the novelty and inventive step of the inventions set forth in claims 1-51.